Bandolier 109

Independent evidence-based health care

On the beach

Not Neville Shute, but a winter break for ***Bandolier***. Beach reading was a superb book on thinking about numbers, involving risk and diagnostic tests. We know that all of us have trouble with probabilities, and odds ratios, and sensitivity and specificity. Different strategies can help most of us overcome these problems. The book is reviewed in this issue, and will be of particular use to tutors for professional development plans. ***Bandolier*** will try to use some of these ideas in future.

On the net - help wanted

There is much new material on the ***Bandolier*** Internet site, including several new resource centres: on aspirin, on needlestick injuries, and on handwashing and infections (in hospital, in healthcare, and in the community). We would like our readers to help in finding good evidence about these latter two topics in particular, because searching is difficult, and much appears in journals that are not in electronic databases. Please help us to help you.

Two new downloadable PDFs, a 22-page essay on acute pain, and another on how to calculate NNTs, plus a single page aide-memoir and calculator. In the first few weeks this has been downloaded several thousand times. We aim to produce more like this, for use in personal and professional development, and to support teachers. ***Bandolier*** would like to know of topics that readers would like to see covered, either specific to EBM, or on covering particilar clinical issues.

Bandolier is updating reviews on topical products, particularly topical NSAIDs and rubefacients. What questions do you want answered in any new review? In primary care these seem to be issues that cause much angst, so let us know the issues ahead of time.

In this issue

Body piercing – prevalence and risks

Bandolier leads a sheltered life. Other than seeing the occasional pierced ear and having a merchant seaman uncle with a few tattoos, the concept of body piercing or tattooing as "body art" is alien. A visit to Oxford's Pitt-Rivers museum reminds one that other cultures at other times have used body art extensively. Readers obviously are not so sheltered, and have asked for the evidence about body art and health.

Prevalence of body piercing

Literature searches found a single study [1], examining body piercing and tattooing in undergraduates at an American university. A single-page questionnaire was refined through a pilot study, and then offered on a voluntary and anonymous basis to students over four months early in 2001. It asked about age and sex, and about body piercing and tattooing at various body sites, as well as about any complications associated with them. Women were specifically asked not to include pierced earlobes.

There were 454 completed questionnaires (218 men, 236 women), about 15% of the total undergraduate population. Their average age was 21 years.

Body piercing

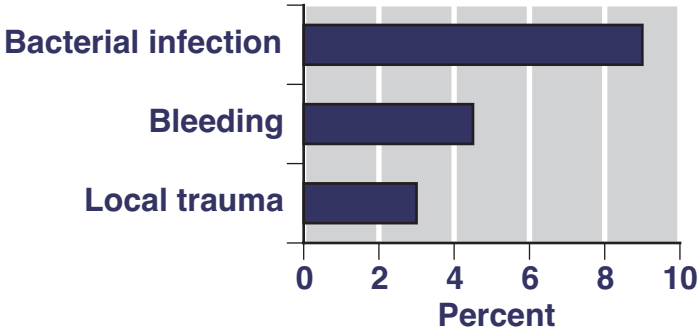
This was present in 42% of men and 60% of women undergraduates, with 315 piercings in 229 students, with a maximum of five piercings.

In men 31% had pierced ears, with tongue, eyebrow, nipple, genitals and navel in 2% or fewer for each. Additionally 7% had had ear piercings removed, and tongue, nipple and navel piercings had been removed in 2% or fewer.

In women 29% had pierced navels, 27% had pierced ears (excluding pierced earlobes), 12% pierced tongue, and 5% pierced nipple, with genitals, nose or lip in 2% or fewer. Additionally 4% had had tongue piercings removed, 3% had navel piercings removed, and ear, eyebrow, nose, lip, nipple and genital piercings had been removed in 2% or fewer.

Complications were reported in 17% of piercings, the most common being bacterial infections, bleeding and local trauma (Figure 1). No cases of viral infection were reported. Tongue piercing was associated with subsequent oral or dental injury in 10%.

Figure 1: Body piercing problems



Tattooing

Tattoos were present in 22% of men and 26% of women undergraduates with one to three sites per individual. Common sites for men were hand or arm, backs and shoulders, and for women back. No complications were noted.

Viral infections and body piercing

One descriptive review [2] has looked at this. It may be a systematic review, but it does not give a search strategy. It included 12 studies published up to 1997 mostly conducted to identify risk factors for viral hepatitis. Three studies were in the USA, four in Italy (by the same investigator) and the remainder in Taiwan, Korea, Thailand and Africa. The size varied from about 110 to over 13,000 subjects.

Nine of the studies, including all the US and Italian studies, and all the largest studies, found body piercing to be a risk factor. The three that did not were all small (fewer than 323 subjects) studies from Taiwan or Korea.

A more recent study has examined risk factors for acquisition of hepatitis C virus infection in the United States [3]. Consecutive chronically infected HCV patients eligible for a clinical trial were recruited, with HBV and HIV as specific exclusions, as was advanced liver disease. A detailed questionnaire about risk factors was completed during an interview with a single investigator.

There were 148 patients (88 men, 60 women) aged 18 to 72 years (mean 45 years). Only 5% had no known risk factor, and the most common known risk factors were injected drug use, sharing razors and toothbrushes, body piercing, being a recipient of blood products, sexual exposure and occupational exposure to blood in 48% to 32% of cases. Tattooing was associated with 17% of cases. Exposure to risk factors differed greatly between men and women, with 92% of women having body piercing (Figure 2). Most cases had more than one risk factor, but in 3 of 23 cases with a single risk factor it was body piercing.

Comment

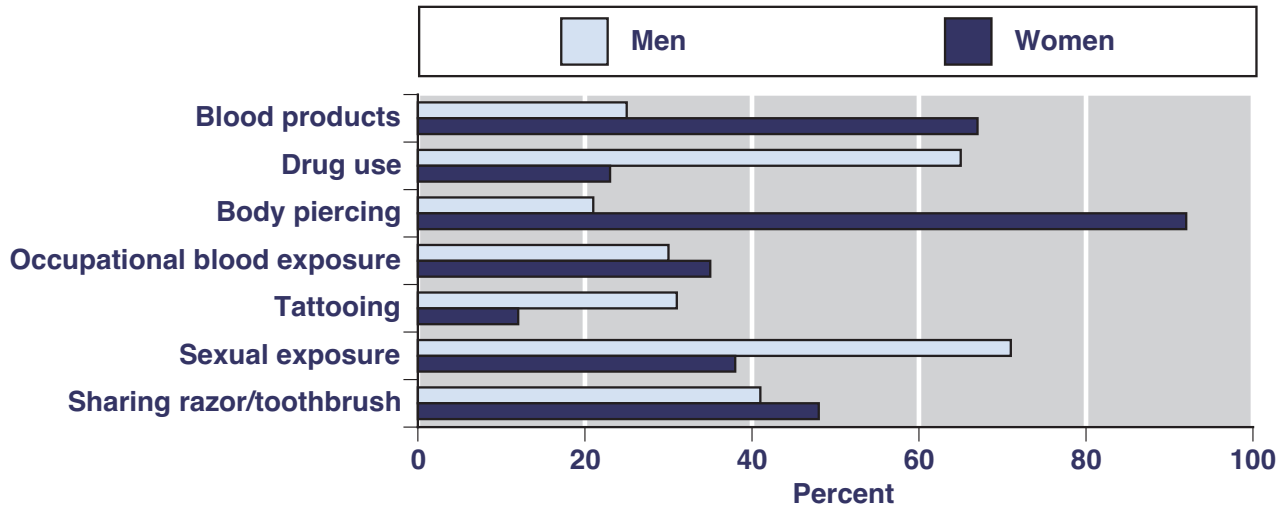
Body piercing is common, and while the only solid evidence we have is that half the undergraduates at a single US university have body piercings, a few hours watching popular television programmes tells us that this is unlikely to be atypical. Adverse happenings with body piercing are also common, affecting about one in five of them. One in ten led to a bacterial infection.

We do not know how many will contract a serious viral infection from body piercing or tattooing. We know that there will be an increased risk. In the meantime, people considering body piercing should be aware that it is more than just a bit of fun. The industry should be careful regulated, single use sterile devices should be mandatory, and HBV vaccination for operators would be a very good idea. In the meantime, a significant public health problem may be silently building up.

References:

1 LB Mayers et al. Prevalence of body art (body piercing and tattooing) in university undergraduates and incidence of medical complications. Mayo Clinic Proceedings 2002 77: 29-34.
2 MO Hayes, GA Harkness. Body piercing as a risk factor for viral hepatitis: an integrative research review. American Journal of Infection Control 2001 29: 271-274.
3 LJ Yee et al. Risk factors for acquisition of hepatitis C virus infection: a case series and potential implication for disease surveillance. BMC Infectious Diseases 2001 1: 8 (www.biomedcentral.com/1471-2334/1/8).

Figure 2: Associations between hepatitis C infection and known risk behaviours



Cannabis and other drug use

Cannabis use is common, particularly among the young. Cannabis has also been seen as leading users into use of "harder" drugs, like cocaine or heroin. There are some studies reporting early use of cannabis as a risk factor for other drugs and drug-related problems. A twin study from Australia that controls for genetic influences [1] confirms this.

Study

The Australian Twin Register is a volunteer panel of twins born between 1964 and 1971. For this study they were interviewed in a single telephone interview in 1996-2000 when the median age was 30 years (range 24 to 36). There were 4010 pairs, with 861 individuals reporting cannabis use before 17 years of age and 2,911 who started using cannabis after 17 years of age.

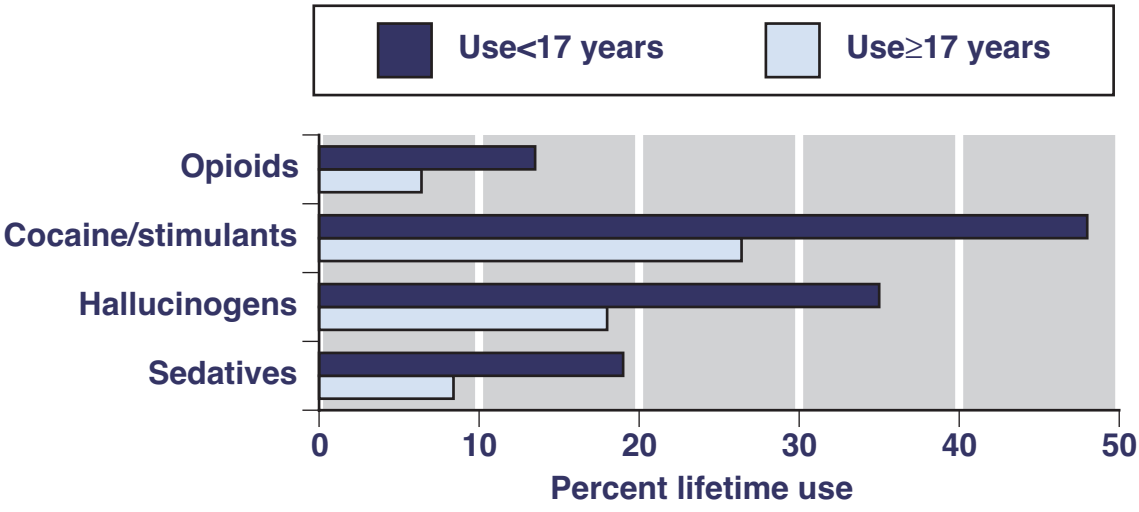
There were 311 twins discordant in the age at which they began using cannabis, and it is these who formed the population for the study. The structured interview was adapted from an assessment of alcoholism, and included information on factors including childhood family environment.

Questions included those regarding lifetime use of drugs in a non-medical context. Those using drugs were additionally asked questions about drug abuse (use in physically hazardous situations, or interfering with major obligations) or dependence (continued use despite problems). Psychiatric disorders, early tobacco use and early regular alcohol use were also questioned.

Results

The first (and interesting) result was that out of 6,265 individuals interviewed 3,772 (60%) reported lifetime use of cannabis. The lifetime use of drugs and of drug abuse or dependence were higher in early cannabis users than in their co-twins who reported later use (Figure 1).

Figure 1: Associations between age of first cannabis use and later use of other drugs



Any illicit drug abuse or dependence was reported by 48% of early cannabis users, compared with 33% for a later using twin. Alcohol dependence was also higher for early cannabis users (43%) than later using twins (30%). The differences were statistically significant for all classes of drug use and abuse, with the exception of abuse of sedatives.

For those who started using cannabis before they were 17 years old the odds of other drug use, alcohol dependence and other drug abuse or dependence were two to five times higher than in co-twins who did not report early cannabis use.

Comment

Any study that uses self-reporting from individuals who claim to be drug users or abusers could be criticised, but this is how much information is collected in this area. These were events occurring in the relatively recent past for these responders, and would be major determinants of their lives. Recall bias therefore seems unlikely.

The evidence is that it is the early use of cannabis, rather than any genetic predisposition that predisposes to later drug abuse and increased use of illicit drugs. Mechanisms are suggested in the paper, but it is because this study was conducted in twins that gives it authority.

Startling is the high prevalence of lifetime cannabis use, which was 60% in 6,265 people questioned. It is also possible to calculate the prevalence of any illicit drug abuse or dependence. There were 311 twins, and 250 individuals had self-reported illicit drug abuse and/or dependence, which is 4.0% of the initial sample. But this is only a sub-sample, because to be in the analysis there had to be twins discordant for early cannabis use.

In total 861 used cannabis before age 17 and 2,911 after 17 years. If the abuse and dependence for twins applied here also, then there would be 410 + 954, or 1,364 people out of 6,265 (22%) reporting illicit drug abuse or dependence in their lifetime. That is a chilling statistic.

Reference:

1 MT Lynskey et al. Escalation of drug use in early-onset cannabis users vs co-twin controls. JAMA 2003 289: 427-433.

Breast cancer, alcohol, and tobacco

One of the most important developments in recent years has been collaboration between research groups to pool information on individual patients better to understand disease development and treatment. One such is investigating breast cancer [1].

Study

The influence of alcohol and tobacco on breast cancer was examined in 65 studies contributing individual patient data on over 66,000 women with breast cancer and nearly 130,000 controls. Of these, 53 had information on both alcohol and tobacco in 58,500 cases of breast cancer and 95,000 controls.

Case-control and cohort studies were eligible if they recruited at least 100 women with invasive breast cancer and recorded information on reproductive factors and use of hormonal therapies. Information on individual women was collated and analysed centrally to use as similar definitions as possible. One drink was 12 grams of alcohol in the USA and Italy, 8 grams in the UK and 10 grams elsewhere.

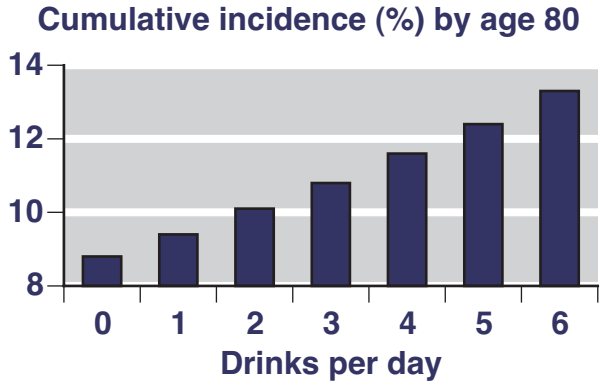
Results

The average age at diagnosis of breast cancer was 52 years. Women with higher alcohol consumption also tended to smoke more in cases and controls. Only 37% of women who never drank alcohol had ever smoked, a proportion rising to about 70% in those with the highest alcohol intake.

In women who had never drunk alcohol (22,000 cases and 41,000 controls) there was no relationship between breast cancer and smoking history (relative risk 1.03). Because of the relationship between increased alcohol consumption and increased smoking, no reliable information could be drawn for smokers who also drank alcohol.

The relative risk of breast cancer was positively linked to increased daily alcohol consumption (Figure 1), to the same extent in women who had never smoked and in those who had ever smoked. Overall, the increase in the relative risk of breast cancer rose by 7% for each 10 grams per day of alcohol intake. There was no significant variation in the trend for any of 15 factors (race, education, BMI, breastfeeding etc).

Figure 2: Cumulative incidence of breast cancer by age 80 and number of drinks per day



The cumulative incidence of breast cancer up to the age of 80 years is between eight and 10 per 100 in women in developed countries. The average consumption of alcohol was 6 grams per day, which would mean that about 4% of breast cancers in developed countries could be attributed to alcohol. The cumulative incidence of breast cancer by 80 years of age for women consuming different levels of daily alcohol a day is shown in Figure 2.

Comment

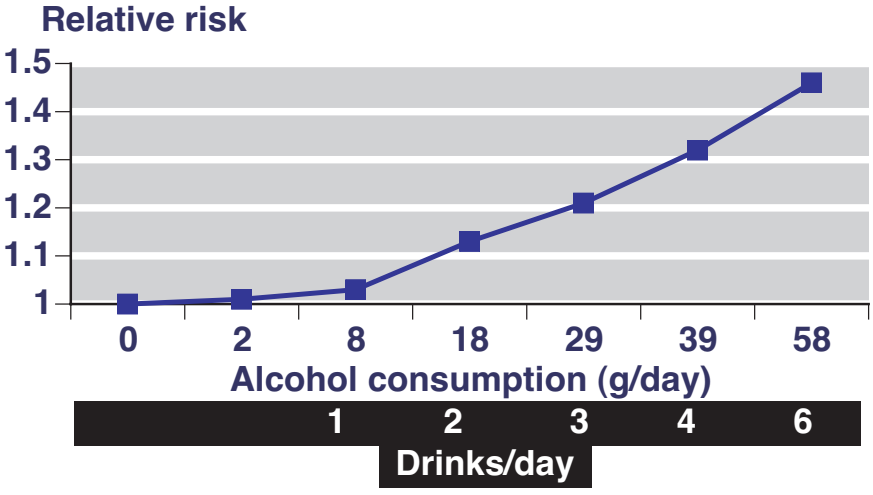
This is fantastic stuff, which can be relied upon because of the mass of information and the quality of the analysis. It firmly makes alcohol an issue for women. It means that benefits of alcohol for the heart have to be balanced against some increased risk of breast cancer.

But at moderate amounts of alcohol, one or two drinks a day, the increase in risk is moderate.

Reference:

1 Collaborative group on hormonal factors in breast cancer. Alcohol, tobacco and breast cancer – collaborative reanalysis of individual data from 53 epidemiological studies, including 58 515 women with breast cancer and 95 067 women without the disease. British Journal of Cancer 2002 87: 1234-01245.

Figure 1: Relationship between daily alcohol consumption and relative risk for breast cancer in women



Treatment protocol for LRTI

Bandolier 101 asked whether treatment protocols delivered better healthcare, mainly from randomised trials. Mostly they did, but more examples would be better. Part of the problem is that assessment of treatment protocols in randomised trials is rare, and other study designs, particularly the before-after design, are used, and may be more appropriate. So we chose as an example a before-after design for treating community acquired lower respiratory tract infection (LRTI) from a hospital in Ulster [1].

Study

The study was conducted in the medical wards of a single hospital in Antrim. All adult patients admitted with a primary diagnosis of LRTI during December 1994 to February 1995 formed the control group. Diagnoses were made on clinical grounds supplemented with X-rays in most cases. Patients received empirical treatment before development of a treatment protocol.

After development and institution of a treatment protocol in November 1995, all patients admitted with a primary diagnosis of LRTI from December 1995 to February 1996 formed the intervention group.

The treatment protocol consisted of measuring the severity of the condition according to age more than 60 years, respiratory rate above 30 breaths/minute, diastolic blood pressure below 60 mmHg, white cell count below 4 or above 20 billion cells/L, new confusion, new atrial fibrillation and multiple lobe involvement on X-ray. One point was given for the presence of each of these, and treatment instituted depending on severity:

- Moderate (score 2 or less): oral amoxycillin/clavulanic acid every 8 hours.
- Severe (score 3 or more): intravenous cefuroxime every 8 hours.
- Very severe (score 3 or more and pO2 less than 8 kPa on 28% oxygen): intravenous cefuroxime every 8 hours and intravenous erythromycin every six hours.

Protocol construction was with involvement and support of all consultant physicians. Introduction involved presentations, seminars and ward discussions, involvement of new junior medical staff, distribution of written summaries of the protocol, posting the algorithm in all wards, encouragement of implementation by clinical pharmacists.

Details of patients and outcomes were collected on a customised data collection form. Treatment success was a major improvement or complete resolution of all signs and symptoms, and failure persistence or progression of signs and symptoms, or development of new clinical findings, or death from the primary diagnosis, or discontinuation of medicines because of adverse reaction.

Results

There were 112 patients in the control group, and 115 in the treatment protocol group. Their mean age was about 68 years, with a mean onset of about five days at admission. Two thirds were moderate and one third severe on admission. There were no differences between the groups, and no patient was very severe on admission. Most patients (99%) had an X-ray. The only significant difference in laboratory testing was that 98% of patients on the protocol had a sputum cultured, while only 55% of controls had this test.

There were 35/112 treatment failures (31%) on control and 9 (8%) on the protocol. The reasons for the failures are shown in Figure 1. Protocol was better than control for every reason for failure. For every four patients on the protocol there was one fewer treatment failure than if the protocol had not been used (NNT 4.3, 95% CI 3.0 to 7.4).

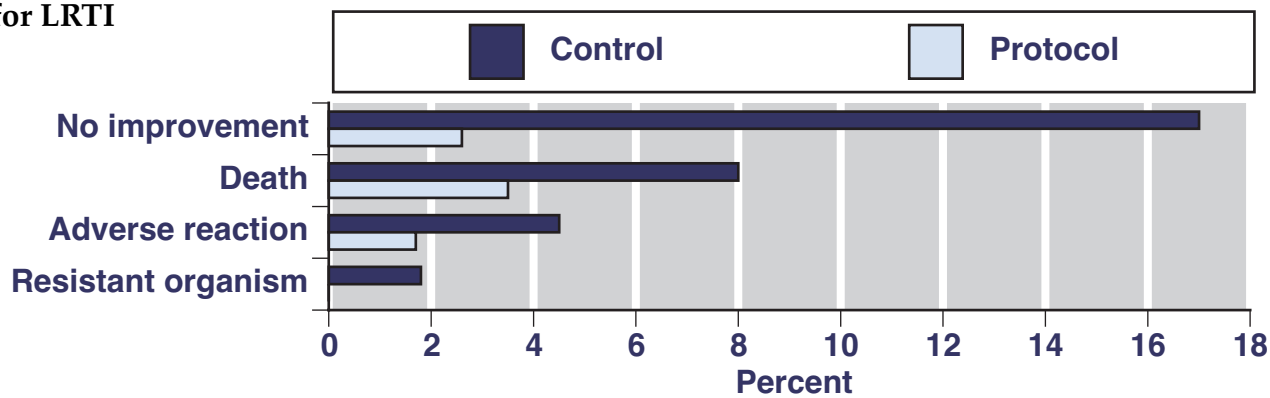
Control patients had a mean length of stay of 9.2 days. Those on the protocol had a mean length of stay of only 4.5 days. The overall average cost per control patient was £2,024 and £1,020 for a protocol patient, a saving of £1,000 per patient. Most savings came from lower bed costs and lower antimicrobial costs (£11 protocol vs £54 control).

Comment

Adopting a treatment protocol delivered better care at lower cost. Protocol construction and implementation was exemplary. This is a study worth reading, though individual hospitals may want to institute different regimens because of local differences.

Reference:
1 FA Al-Eidan et al. Use of a treatment protocol in the management of community-acquired lower respiratory tract infection. Journal of Antimicrobial Chemotherapy 2000 45: 387-394.

Figure 1: Results in Antrim before and after protocol for LRTI



RIGHT TREATMENT, RIGHT PATIENT

In his ground-breaking classic book on evidence-based healthcare [1], Muir Gray has a chapter entitled "Doing the right things right". It is always worth re-reading, and it is also worth extending, perhaps to whether we do the right things, to the right patients, at the right time, and do we do them right? An intriguing study from Norway suggests that treating the right patient right can have real benefits [2].

Study

Actually there were two studies in one. The main study looked at different levels of intervention for people off sick from work with musculoskeletal problems for more than eight weeks. The subsidiary study examined the effectiveness of treatment depending on an initial prognosis determined by a screening instrument.

The setting was the area around Bergen, with a population of 270,000. Participants were recruited from sickness insurance records if they were off work for eight weeks or more. The total approached was 1,988 (0.74% of the total population). Because some people did not accept the invitation to participate, the final sample was 654 individuals (33% of the total).

Screening instrument

This consisted of a questionnaire and a structured examination by a physiotherapist. The details are too many to explain here, but in a fairly simple process participants were graded as having a good, medium or poor prognosis to return to work.

Randomised trial

A properly randomised open study involved three treatments:

1 Ordinary treatment described referral back to a general practitioner.
2 Light multidisciplinary treatment and follow up comprised a lecture on exercise and lifestyle and fear avoidance advice, with information and feedback. Patients were encouraged gradually to increase their activity level. Patients received individual exercise programmes. Some were referred to physiotherapists. Over a year each patient received an average of three individual follow ups.
3 Extensive multidisciplinary treatment and follow up involved a more intensive treatment program lasting for four weeks, with six hour sessions five days a week. It involved cognitive-behavioural modification, education, exercise and occasional workplace interventions. Patients were encouraged to take responsibility for their own health and lifestyle. Follow up over one year with individual pain management programmes.

The outcome was return to work by one year after the intervention, which took place about two months after screening. A cost benefit analysis was also carried out for the light and extensive multidisciplinary treatments. Economic returns were measured in terms of productivity gain when patients returned to work minus the costs of the treatment programmes.

Results

At baseline the three treatment groups were well matched. The mean age was 44 years, about two thirds were women, and three quarters of patients had back pain or neck or shoulder pain. About half were considered to have a medium prognosis for return to work, 22% had a good prognosis and 28% a poor prognosis. More patients had returned to work at one year with a good prognosis or medium prognosis than with a poor prognosis (Table 1).

Table 1: Return to work and initial prognosis

Initial prognosis	Percent in work at one year
Good	61
Medium	57
Poor	44

Ordinary treatment led to fewer patients at work at one year (50%) than either the light or extensive multidisciplinary treatments (60%).

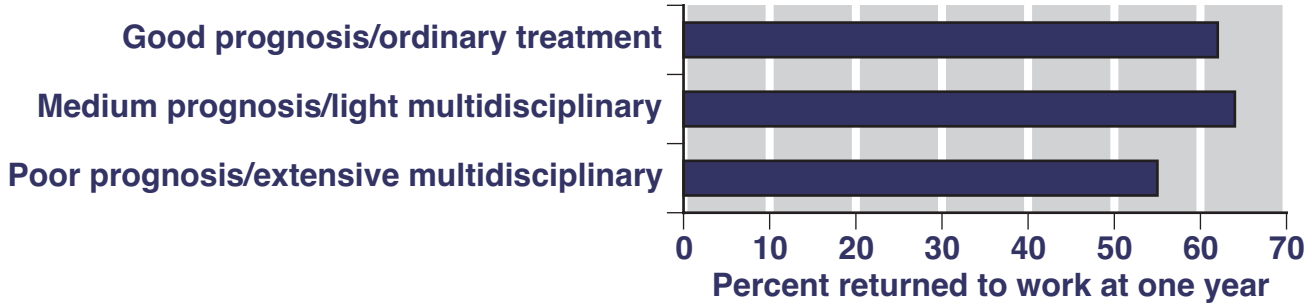
- For patients with a good prognosis, there was no difference between treatments.
- For patients with a medium prognosis there was no additional effect of extensive over light multidisciplinary treatment. Ordinary treatment for these patients gave poor results (Table 2).
- For patients with poor prognosis extensive multidisciplinary treatment was superior to ordinary or light multidisciplinary treatment (Table 2).

Most patients returned to work if they were given treatment appropriate to their screening category (Figure 1). Between 55% and 64% returned to work when given the right treatment.

Table 2: Results of different treatment strategies with medium and poor prognosis

	Percent in work at one year		
Initial prognosis	Ordinary treatment	Light multidisciplinary	Extensive multidisciplinary
Medium	48	63	62
Poor	37	44	55

Figure 1: Treating the right patients right



If screening results rather than randomisation had been the determining factor for the type of treatment, then productivity gains would have outweighed the cost of treatment by $800 per treated patient.

Comment

What we have here is a demonstration from a randomised trial that doing the right thing for the right patient pays dividends. The benefits are to the patients who get back to work, and benefit because of it, and society, which benefits because the productivity gains outweigh the costs of getting people back to work. Whether this would be true in societies other than Norway is another matter.

The general principle seems sound. One size does not fit all, and the average results from studies need not apply to individuals. It sounds more complicated, but actually is not. It comes down to a greater appreciation of the benefits of triage, or diagnosis, or prognosis. All topics where evidence is painfully thin.

References:
1 JA Muir Gray. Evidence-based healthcare. Churchill Livingstone, 1997. ISBN 0-443-05721-4.
2 EM Haland Haldorsen et al. Is there a right treatment for a particular patient group? Comparison of ordinary treatment, light multidisciplinary treatment, and extensive multidisciplinary treatment for long-term sick-listed employees with musculoskeletal pain. Pain 2002 95: 49-63.

Echinacea treatments for colds

One of the problems with complementary therapies is the absence of high quality trials. Systematic reviews that include poor quality trials have a propensity to mislead, because poor trials are often more positive in their outcomes. The best and most recent systematic review for echinacea treatment [1] had nine trials (1,264 subjects) assessing cold treatment with echinacea with a number of different products. The studies assessed patients over different duration (8 days to resolution of symptoms). Six trials showed modest, but significant improvement in symptoms over placebo (or vitamin C).

Despite this the beneficial effects of echinacea for the early treatment of colds were modest and there was no convincing evidence of its effectiveness in the prevention of colds. The trials were generally of medium to poor quality, though they were mostly of reasonable size (over 100 patients per group).

With this background, we should examine any new high quality trial to see whether it enhances or deflates the modest claims of efficacy. One such study [2] is highly deflating.

Study

The study was properly randomised, properly blinded, and told us what happened to each patient in some detail. Treatments, active and placebo, were tested on volunteers to see if they could tell the difference – they could not. The paper is a model of reporting quality. In addition, the echinacea used in the study was subjected to chemical and biological activity, so that we know that it had active ingredients, and that those active ingredients caused expected changes in biological systems.

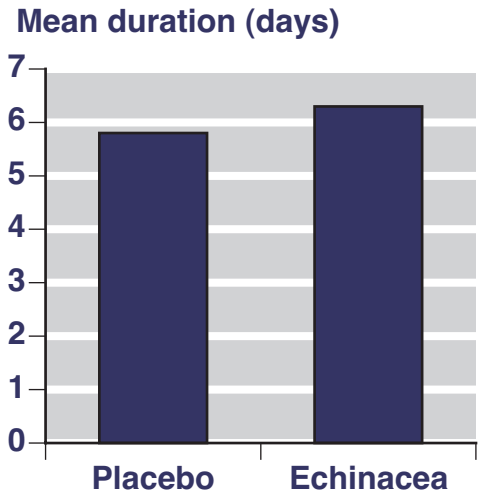
Participants were students at a US university recruited over a winter cold season. Advertisements asked respondents to call a number at the first sign of flu-like symptoms. These were screened first by telephone, and then by interview, all within a few hours of first contact. To be included subjects had to be over 18 years, to suspect they were coming down with a cold, to report at least two of 15 symptoms, one of which had to be specific to the respiratory tract, and to be willing to adhere to the protocol. Exclusions were symptoms established for more than 36 hours, pregnancy, and current use of antibiotics, antihistamines or decongestants.

The primary outcomes were the severity and duration of self-reported symptoms, collected both by paper and web-based instruments. The study was powered to detect a two-day difference in duration or a two point (out of four) difference in severity.

Results

There were 148 participants (mean age 21 years), and echinacea and placebo groups were well matched, including use of non-protocol medicines. Information collection

Figure 1: Cold duration with echinacea and placebo



was almost 100% and adherence to tablets was 92% by counting returned bottles.

There was no difference in cold duration (Figure 1), which ranged from two to 10 days. It was 5.8 days for placebo and 6.3 days for echinacea.

There was no difference in severity of any of 15 symptoms or of global severity at any time.

Some adverse events were reported by both groups (22 in 15 participants), with no difference between the groups.

Comment

Echinacea had absolutely no effect in this trial. Why not? Perhaps because echinacea does not work. Systematic reviews of generally low quality trials that probably have some bias can only show a modest effect, and this high quality study erodes that even further.

Three species of Echinacea are used in medicine: purpurea, angustifolia and pallida. It contains flavonoids, glycoproteins and a variety of other active components which are thought to stimulate the immune system. Extracts can be derived from the whole plant, roots or flowers and other plant extracts or homeopathic compounds may be added. The specific combination in this trial was purpurea whole plant and angustifolia root.

It is possible that there are other combinations that might yet have a modest effect, perhaps in other populations than young, otherwise healthy, undergraduates. But don't bet on it. Right now the best evidence is that echinacea is useless, and money spent on it is wasted.

References:
1 B Barrett et al. Echinacea for upper respiratory infection. Journal of Family Practice 1999 48: 628-635.
2 BP Barrett et al. Treatment of the common cold with unrefined echinacea. A randomised, double-blind, placebo-controlled trial. Annals of Internal Medicine 2002 137: 939-946.

Book review

Reckoning with Risk. Gerd Gigerenzer. Penguin Books Ltd, London, 2002. 250pp, plus glossary notes etc, £14.95.

This is a great book, and you should read it. Yes, it does give a bit of a puff to ***Bandolier***, but that's on page 239 out of 250 pages of text, so clearly it grabbed our attention. It is readable, and a bit of fun, and concentrates on making numbers understandable. If you have had trouble understanding the numerical results of trials or especially diagnostic screening tests, this book will demystify it for ever.

Gigerenzer is the Director of the Centre for Adaptive Behaviour and Cognition at the Max Planck Institute in Berlin, and former professor of psychology at Chicago University. He starts with the premise that, whatever we claim we think we know, when you test us, we don't. Throughout he gives results of tests on how well doctors understand information given to them.

Unsurprisingly, most times doctors haven't a clue, and most of them misunderstand results presented in standard forms using probabilities. But give them frequencies and a simple tool to help them think about what's actually going on, and almost all of them get it right. There are references for all this, so we can chase up the papers and read them in detail.

And there are examples, including breast cancer screening, informed (or uninformed) consent, AIDs counselling, wife battering, expert witnesses who aren't expert, DNA fingerprinting, and violence. Some of them might make you sit up and think. ***Bandolier*** thought those on breast cancer screening and DNA fingerprinting particularly illuminating.

So what's the secret? Gigerenzer uses "natural frequencies". He proposes a simple diagrammatical representation of what is happening to work out what is going on. For breast cancer screening, for instance, he helps us recognise that t a woman screening positive on mammography has only a 1 in 10 chance of actually having breast cancer. The whole chapter should be taken and reproduced for women considering screening, and the professionals who have to advise them.

Medical writers, from academics through editors to journalists, should read this book and keep it by their side. ***Bandolier*** certainly will. It ranks alongside the ***Economist*** style guide as an essential tool of the trade.

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